CAPSTONE® Spinal System
510(k) Summary

June 12, 2012

AUG 29 2012

I. Company:

Medtronic Sofamor Danek USA, Inc.
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Contact: **Mr. Brad Sheals, MS**
Senior Regulatory Affairs Specialist

II. **Proprietary Trade Name:** CAPSTONE® Spinal System

III. **Classification Name:** Intervertebral Body Fusion Device (21 CFR 888.3080)

IV. **Product Code:** MAX

V. **Product Description:**

The purpose of this 510(k) submission is to include additional sizes of PEEK cages, an inserter and to make minor clarifications to the CAPSTONE® Spinal System IFU.

The CAPSTONE® Spinal System consists of Polyetheretherketone (PEEK) cages, titanium alloy and titanium cages of various widths and heights, which can be inserted between two lumbar or lumbosacral vertebral bodies to provide support and correction of the lumbar spine during lumbar interbody fusion surgeries. The hollow geometry of the CAPSTONE® implants allows them to hold autogenous bone graft material.

VI. **Indications:**

The subject CAPSTONE® Spinal System has the identical indications for use as the predicate CAPSTONE® Spinal System. The CAPSTONE® Spinal System is indicated for interbody fusion with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two levels from L2 to S1. These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and

radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants may be implanted via an open or a minimally invasive posterior approach. Alternatively, these implants may also be implanted via an anterior and/or transforaminal approach. These implants are to be used with autogenous bone graft. These devices are intended to be used with supplemental fixation instrumentation, which has been cleared by the FDA for use in the lumbar spine.

VII. Identification of Legally Marketed Predicate Devices Used to Claim Substantial Equivalence:

The design features, materials and indications for use of the CAPSTONE® Spinal System are the same as the predicate CAPSTONE® Spinal System components previously cleared in K073291 (S.E. 04/24/2008). Additional predicates such as the CAPSTONE® Spinal System (i.e. K103731, S.E. 07/18/2011), CAPSTONE CONTROL™ Spinal System (i.e. K120368, S.E. 04/09/2012) and the CRESCENT® Spinal System (i.e. K110543, S.E. 08/09/2011 and K094025, S.E. 04/26/2010) were also utilized to support the safety and effectiveness of the modified subject PEEK cages and inserter within this premarket notification.

VIII. Summary of the Technological Characteristics:

The purpose of this 510(k) is to add additional sizes of PEEK cages, an inserter and to make minor clarifications to the CAPSTONE® Spinal System IFU. The subject and predicate CAPSTONE® PEEK cages and inserter are identical in terms of indications for use, intended use, performance specifications and technological characteristics. The key difference between the subject and predicate device are the additional widths of the PEEK cage and a new inserter specific to the subject device.

IX. Discussion of Non-Clinical Testing:

The subject PEEK cages were tested using bench performance testing (i.e. ASTM F2077-03 and ASTM F2267-04) compared to the predicate device. Testing of the subject PEEK cages supports that the subject devices are as safe, as effective and perform as well as the predicate device(s).

X. Discussion of Clinical Testing:

No clinical testing was performed.

XI. **Conclusions Drawn from the Non-Clinical Tests:**

Based on the test results and additional supporting documentation provided in this premarket notification, the subject devices demonstrated that they are as safe, as effective and perform as well as the predicate device(s).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Medtronic Sofamor Danek USA, Incorporated
% Mr. Brad Sheals
Senior Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

AUG 29 2012

Re: K121760
Trade/Device Name: CAPSTONE® Spinal System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: August 15, 2012
Received: August 16, 2012

Dear Mr. Sheals:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K121760

Device Name: CAPSTONE® Spinal System

Indications for Use:

The CAPSTONE® Spinal System is indicated for interbody fusion with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two levels from L2 to S1. These DDD patients may also have up to Grade I Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants may be implanted via an open or a minimally invasive posterior approach. Alternatively, these implants may also be implanted via an anterior and/or transforaminal approach. These implants are to be used with autogenous bone graft. These devices are intended to be used with supplemental fixation instrumentation, which has been cleared by the FDA for use in the lumbar spine.

Prescription Use _X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121760